UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

STEPHEN CROCKER, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. CASSAVA SCIENCES, INC., RICHARD JON BARRY, and JAMES W. KUPIEC, Defendants.	Case No. 1:24-CV-1525 **COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **CLASS ACTION** Demand for Jury Trial

Plaintiff Stephen Crocker ("Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, alleges in this Complaint for violations of the federal securities laws (the "Complaint") the following based upon knowledge with respect to his own acts, and upon facts obtained through an investigation conducted by his counsel, which included, *inter alia*: (a) review and analysis of relevant filings made by Cassava Sciences, Inc. ("Cassava" or the "Company") with the United States Securities and Exchange Commission (the "SEC"); (b) review and analysis of Cassava's public documents, conference calls, press releases, and stock chart; (c) review and analysis of securities analysts' reports and advisories concerning the Company; and (d) information readily obtainable on the internet.

Plaintiff believes that further substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. Most of the facts supporting the

allegations contained herein are known only to the defendants or are exclusively within their control.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Cassava securities between February 7, 2024 to November 24, 2024, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws (the "Class").

2. Defendants provided investors with material information concerning Cassava's leading drug candidate, simufilam. Defendants' statements included, among other things, clear confidence in simufilam's ability to treat Alzheimer's Disease through the promotion of statistically insignificant phase 2 results, patient elected enrollment in the open-label expansion studies, and the presentation of detailed plans for the future of the company upon the conclusion of successful Phase 3 studies showing the effectiveness of simufilam, coupled with the absence of any detailed plan for the alternative scenario arising out of the drug's failure.

3. Defendants provided these overwhelmingly positive statements to investors while, at the same time, disseminating materially false and misleading statements and/or concealing material adverse facts concerning the true capabilities of Cassava's drugs; notably, that Company simply did not have a drug that was capable of abating the progression of Alzheimer's Disease. Such statements absent these material facts caused Plaintiff and other shareholders to purchase Cassava's securities at artificially inflated prices.

4. On November 25, 2024, Cassava released topline results for the first of its two ongoing Phase 3 studies on simufilam, the "ReThink-ALZ" study. The results indicated that

simufilam failed to meet each of the pre-specified primary, secondary, and exploratory endpoints; in sum, simufilam failed to outperform the placebo.

5. Investors and analysts reacted immediately to Cassava's revelation. The price of Cassava's common stock declined dramatically. From a closing market price of $26.48 per share on November 22, 2024, Cassava's stock price fell to $4.30 per share on November 25, 2024, a decline of about 83.76% in the span of just a single day.

JURISDICTION AND VENUE

6. Plaintiff brings this action, on behalf of himself and other similarly situated investors, to recover losses sustained in connection with Defendants' fraud.

7. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. §78aa.

9. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b), as Defendant Cassava is headquartered in this District and a significant portion of its business, actions, and the subsequent damages to Plaintiff and the Class, took place within this District.

10. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

THE PARTIES

11. Plaintiff purchased Cassava common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the Defendants' fraud. Plaintiff's certification evidencing his transaction(s) in Cassava is attached hereto.

12. Cassava Sciences, Inc. is a Texas corporation with its principal executive offices located at 6801 N. Capital of Texas Highway, Building 1, Austin, TX 78731. During the Class Period, the Company's common stock traded on the NASDAQ Stock Market (the "NASDAQ") under the symbol "SAVA."

13. Defendant Richard Jon Barry ("Barry") was, at all relevant times, a Director of Cassava. Barry became the Executive Chairman July 17, 2024, before being promoted to the role of Chief Executive Officer of Cassava on September 9, 2024.

14. Defendant James W. Kupiec ("Kupiec") was, at all relevant times, the Chief Medical Officer of Cassava

15. Defendants Barry and Kupiec are sometimes referred to herein as the "Individual Defendants." Cassava together with the Individual Defendants are referred to herein as the "Defendants."

16. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Cassava's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual Defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these Individual

Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

17. Cassava is liable for the acts of the Individual Defendants, and its employees under the doctrine of respondeat superior and common law principles of agency as all the wrongful acts complained of herein were carried out within the scope of their employment with authorization.

18. The scienter of the Individual Defendants, and other employees and agents of the Company are similarly imputed to Cassava under respondeat superior and agency principles.

SUBSTANTIVE ALLEGATIONS

Company Background

19. Cassava is a clinical stage biotechnology company, with a focus on developing drugs for neurodegenerative diseases.

20. Cassava's leading therapeutic candidate is simufilam, a proposed treatment for mild to moderate Alzheimer's Disease.

The Defendants Materially Misled Investors Concerning the potential for Cassava's drug, simufilam, to be Effective as a Treatment for Alzheimer's Disease

February 7, 2024

21. On February 7, 2024, Defendants issued a press release announcing topline results for a Phase II study designed to investigate the safety of drug, simulfilam, as a treatment for Alzheimer's disease dementia.

22. The Company published results as follows:

- Patients with mild Alzheimer's disease who received simufilam treatment continuously for two years (n=47) had no decline in ADAS-Cog scores (± 1.51 SE) as a group.
- Patients with mild Alzheimer's who received simufilam treatment non-continuously (n=40) declined 1 point on ADAS-Cog (± 1.65 SE) as a group. Non-continuous treatment consisted of one year on open-label drug, six months on placebo and six months back on open-label drug.
- In patients with mild Alzheimer's, the largest separation between the continuous and non-continuous treatment groups occurred at the end of the 6-month randomized, placebo-controlled withdrawal phase.
- Patients with moderate Alzheimer's who received simufilam treatment continuously for two years (n=32) declined 11.05 points on ADAS-Cog (± 1.91 SE) as a group.

. . .

The safety study was conducted in three continuous phases:

- a 12-month, open-label treatment phase, followed by
- a 6-month randomized, placebo-controlled withdrawal phase, followed by
- 6 additional months of open-label treatment

23. Then-President and CEO Remi Barbier stated, Cassava is "fighting Alzheimer's disease by testing simufilam, a new type of drug that has a completely different mechanism of action from monoclonal antibody drug treatments … Stable ADAS-Cog scores over 2 years is clearly a desirable clinical outcome in Alzheimers. Our data in mild patients may emphasize the importance of treating patients early in the disease"

May 10, 2024

24. On May 10, 2024, the Company published its Q1FY24 financial results and provided clinical updates on the ongoing Phase 3 trials. The company briefly detailed the Phase 3 studies as follows:

> Phase 3 Trials – Our first Phase 3 study, called RETHINK-ALZ, is designed to evaluate the safety and efficacy of simufilam 100 mg tablets twice-daily versus matching placebo over 52 weeks (NCT04994483). Our second Phase 3 study,

> called REFOCUS-ALZ, is designed to evaluate the safety and efficacy of oral simufilam 100 mg and 50 mg tablets twice-daily versus matching placebo over 76 weeks (NCT05026177).

25. The Company further, while reiterating the studies were fully enrolled, indicated the "drop-out rate for both Phase 3 studies is in the range of 20% to 22%, which is generally consistent with expectations." By this time "Over 435 patients have completed the 52-week RETHINK-ALZ study" and another 300 completed the REFOCUS study. The Company also detailed an open-label extension study available to participants of the Phase 3 studies, noting "Approximately 90% of patients who've completed treatment in a Phase 3 study have opted to enter the open label extension study. To date, over 655 patients [of the 735 completed participants] have opted to enter the open-label extension study."

June 28, 2024

26. On June 28, 2024, Cassava issued a statement on former science advisor, Dr. Wang, stating, in pertinent part:

> Cassava Sciences, Inc. … reported it has learned today that a federal grand jury returned an indictment charging Hoau-Yan Wang for allegedly defrauding the U.S. National Institutes of Health (NIH). Hoau-Yan Wang was a … former paid science advisor to Cassava Sciences.
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> According to public court documents, Dr. Wang engaged in illegal behavior to defraud the government through grant applications made to the NIH, resultin gin the award of approximately $16 million in grants approximately 2017 to 2021 on behalf of himself and the Company. Wang's work under these grants was related to the early development phases of the Company's drug candidate and diagnostic test and how these were intended to work.
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> Dr. Wang and his former public university medical school have had no involvement in the Company's Phase 3 clinical trials of simufilam.

July 17, 2024

27. On July 17, 2024, the Company jointly announced the immediate resignation of Remi Barbier as President and CEO of the Cassava and the appointment of Richard (Rick) Barry as Executive Chairman and principal executive officer while the Company looks for a new permanent CEO.

28. Regarding the appointment, Executive Chairman Barry stated, "While our priority remains the development of a potentially effective treatment for Alzheimer's disease, the Board has a steadfast commitment to doing so with transparency, accountability, and highest ethical business practices."

July 30, 2024

29. On July 30, 2024, Cassava announced the expansion of its open-label extension trials by "up to an additional 36 months" in "each of the open-label extension trials in its ongoing Phase 2 and Phase 3 clinical programs." These extension trials permit patients who participated in the randomized or open-label trials to continue treatment on simufilam.

30. Notably, the Company touted that ***"[a]pproximately 89% of patients in Cassava's ongoing Phase 3 program have elected to continue with open-label treatment with simufilam after completion of the blinded trials,"*** suggesting the patients in the trial believe the drug to be working.

August 8, 2024

31. On August 8, 2024, Cassava held published their "Q2 2024 Financial Results and Operational Updates" and conducted a corresponding earnings call. During the call, Executive Chairman Barry provided confidence in simufilam's success in Phase 3, stating, in pertinent part:

> ***Now we must plan for success. Continuing our open-label extension trials was one way for planning for success.*** But in the coming months, you will see others.

> You will notice an uptick in our R&D spending during the second half of the year. Some of that increased spending will be devoted to preparation for the commercial launch of our drug. We are currently ramping up our active pharmaceutical ingredient purchases, securing increased outsourced manufacturing capacity and exploring distribution capabilities. ***We have to plan for Cassava's successful transition from a development stage company to a commercial enterprise. What we cannot accept is for us to fail the drug. There is an overwhelming need for Alzheimer's patients to have a drug that has the profile that simufilam has displayed so far in its development. We cannot let patients and their loved ones down***.
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> In today's press release, we discussed the $40 million reserve we are taking for potential settlement with the Securities and Exchange Commission. This statement does not mean that we have an agreement in principle with the SEC yet, but it does mean that we now have enough information to understand what our exposure could be, if we do come to a resolution with the SEC that will end their investigation of the company. I should add that we are continuing to have constructive conversations with both the SEC and the Department of Justice. There really isn't more we can say about this now, but we hope to be able to do so before long. We are not taking a charge of this magnitude lightly. $40 million is an awful lot of money for anyone, let alone a company of our size. ***But it is our goal to put our path behind us and focus entirely on our mission, developing a best-in-class treatment for Alzheimer's patients***.

32. Dr. James W. Kupiec, Cassava's CMO, details the Phase 3 studies and his belief in Simufilam, stating in pertinent part:

> When I led these Phase II and Phase III programs in the past, we frequently did not know until the end of the large Phase III study that the drug had failed. And this was always sad for both patients and everyone involved in research efforts. Drug development for neurologic diseases began to change dramatically around 2018 with the advent of ultrasensitive fluid-based biomarkers, a technologic advancement that many have characterized as the biomarker revolution for brain diseases. Biomarkers allow us to examine the machinery inside the cells -- brain cells of patients with Alzheimer's disease
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> . . .
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> ***Patients in both Phase III studies have the option then of rolling over into the open-label extension study. And as Rick shared, some 89% of patients have elected to do just tha***t. As Chief Medical Officer for Cassava, I'm ultimately responsible for the safety of these patients, and I spend a lot of time reviewing all types of safety, lab and ECG reports, along with the medical monitor of Premier. When a patient reports a new medical condition or a symptom, this is called an adverse event for the purpose of regulatory filings. I am pleased to report that no

> serious adverse event has yet been linked to study drug in any of our Phase II or Phase III studies. A huge amount of safety data has now been shared on 2 separate occasions with the Data and Safety Monitoring Board, or DSMB, who have instructed us to continue the studies without change.
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> ***That's my update for Phase III that I want to share***, but if I may, I'd like to share a final personal note***. I was excited when I joined Cassava, but I'm even more excited and optimistic now about simufilam and its chance of success in Phase III.*** Simufilam continues to be safe and well tolerated in a very large number of patients. Plus ***the data from the 24-month open-label Phase II safety study was remarkable in that patients with mild dementia apparently had no significant decline during that 2-year treatment period. If this is true and replicated in Phase III, it would represent an exceptional achievement in a significant event in the field.***

(Emphasis added).

33. A question-and-answer segment followed the Defendants' prepared remarks, during which they spoke more on the ongoing Phase 3 trials, particularly related to patient dropout rates and the open-label extension trials, in pertinent part as follows:

> <Q: Soumit Roy – JonesTrading Institutional Services, LLC – MD, Director of Research & Healthcare Analyst> Thank you for providing all the details, Rick. One -- 3 questions. One is on the discontinuation, dropout rate of about 20% to 22%. Could you describe us what was the key driver for that? Was it dose reduction, discontinuation due to AE or any controversy related to the drug? Any details would be greater.
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> <A: James W. Kupiec> Yes . . . The first question was about the dropout rate. ***Dropout rate that we've seen in both of the 2 studies is about 20%, slightly more than 20% in the longer study. As is common in these studies, the most typical reason for a dropout is because, what I call study fatigue, patient fatigue***. The withdrawal consent patients are moving someplace. It's not just a patient-involving study, but also a partner, a study partner. And they oftentimes are just weary from coming back and forth, back and forth through research center.
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> So if you look at, let's say, other studies that have recently been reported and approved by FDA such as aducanumab or lecanemab or danatumab, again, the most common reason for dropouts is not adverse events but withdrawal of consent.

. . .

<Q: Elemer Piros – Rodman & Renshaw – Analyst> Okay. And maybe one last question to Rick. You alluded to that there was a demand to expand the expanded access program to be under 1 year. What precipitated that? Was it more like clinicians demand or patient/family demand that you observed? If you could provide a little bit of color there.

<A: Richard Jon Barry> I think the honest answer is it was a lot of things***. So we heard from the sites that patients were going off and they wanted to stay on the drug. We heard that loud and clear through the clinical team.*** And I got to tell you, I ***have received quite a few e-mails from the patient community generally from loved ones of patients who are on the drug or on the -- that were on the trial are now in the extension trial. And they weren't begging to continue, but they very clearly wanted to continue***. They understood the constraints of us being a small company and this being very costly. So it was a lot of things that led to it. But like I said, it was an easy decision. I mean the -- ***it's just the right thing to do for patients. And to me, it struck me as cruel to have somebody on a drug for that long and they think that they're getting a benefit from it, and we're taking them off***. So -- it's driven by a lot of factors.

<Q: Elemer Piros> Yes. And Rick, I can imagine that you received quite a bit of an interest, I mean, this is one of the only handful of pivotal programs ongoing in Alzheimer's from potential partners. Can you describe some of the dynamics of those in the past? And what would be your anticipation once data is available.

<A: Richard Jon Barry> Yes. I don't think I want to go too far into it. But the -- realistically, I would not expect us to see -- I wouldn't expect to see a partnership before we have Phase III data. And if you think about it from the other side, this is a big pharma company, some business development officer would have to take the risk of walking into a CEO's office and saying, "Hey, I want to make a bet on this company. We don't have data yet." Most of the deals you see with big pharma these days are very expensive, and they're expensive because they're risk averse and they wait until there's a Phase III result or there's an FDA approval. So it's, I guess, the best I could say. Stay tuned.

(Emphasis Added).

September 9, 2024

34. On September 9, 2024, Cassava appointed Richard (Rick) Barry to the permanent CEO position.

September 24, 2024

35. On September 24, 2024, Cassava presented at the H.C. Wainwright Conference in the form of a "Fireside Chat." During the presentation, CEO Richard Barry spoke at length about Simufilam's background research and the Company's excitement and anticipation for the topline results of the first Phase 3 study, in pertinent part as follows:

> Yeah, well you know. In terms of the proof, whether its going to provide that efficacy or not, we're gonna find out pretty shortly when we have the first phase 3 readout, which will be by the end of this year. But the mechanism of action is different. Typically, you know we've seen for years and years large pharmaceutical companies have been doing phase 3 trials for Alzheimer's drugs, generally they've gone after drugs that have targeted – are targeting amyloid plaque and trying to remove amyloid plaque from the brain. And up until recently those trials, you know, consistently failed.
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> ***This is a different way of approaching the disease***. So the theory behind the method of action is that amyloid beta 42 binds to the A7 receptor in the brain. And what seems to enable that binding and cause the problem in the brain is it recruits this large protein, large scaffolding protein filamin a. And when filamin a gets in the picture that's when all the phosphorization starts to happen down the track. ***So this, you know and - what we've seen so far, phase 2 results is, this to me was, you know, very impressive and one of the reasons I'm here***, is that in the phase 2, you know, we started with 216 patients and it was, you know, there were certainly weaknesses in the trial: it was open label, everybody knew they were getting the drug, but after 12 months there were 216 patients. After 12 months, patients were given the option of remaining on the drug or terminating the trial, or if they wanted to remain on the drug the way to do it was 50% of those would be assigned to a placebo group for 6 months and 50% would stay on the drug. And then after that additional 6 months, everybody would be back on the drug. ***And what was persuasive about that trial, at least to me, was that the uh – at the end of 2 years the mild patients in the trial showed virtually no cognition decline. I mean that is unheard of. And, you know, again, there are weaknesses: phase 2 trial, open label, but uh – nobody has seen results like that before.***
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> . . .
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> ***We're really excited to see the data. It's uh, you know, again, we look the - at what we saw in phase 2, we look at what we've seen in biomarkers, we look at the method of action. If this works this will be – you know this could be a disease modifying drug that treats Alzheimer's and it may have – so far what we've seen is a safety profile that's just really pristine***

. . .

> ***One thing I didn't mention, and I probably should have was, in that phase 2, when the patients when into that period where, you know, half of them were stayed on the drug and half went off. I actually found that really persuasive again, its – we're going to see in phase 3 whether that holds up. The interesting thing is the patients that went on placebo for six months, they did decline, but they didn't decline very much. To me, again I'm not a scientist, so take this with a grain of salt, that would suggest to me that the drug might actually have disease modifying qualities, because the patients should have declined a lot faster. We'll see.***

October 8, 2024

36. On October 8, 2024, Cassava published "An Open Letter from President and CEO Rick Barry to the Cassava Community," detailing the Company's progress over the last "few months." In his letter, CEO Barry spoke to the SEC settlement regarding the Phase 2b study and downplayed the test's importance, reiterated the significance of the Phase 2 safety study, and reinforced the purportedly solid basis for Simufilam as a treatment for Alzheimer's, while appearing to hedge on the possibility of a failure in the Phase 3 study:

> [W]e made the difficult, but appropriate, decision to enter a settlement with the Securities and Exchange Commission. In sum, we have been able to put the SEC's three-year investigation of Cassava behind us by agreeing to settle a charge of negligently making inaccurate disclosures related to our 2020 Phase 2b clinical study and paying a $40 million monetary penalty. In addition, we do not anticipate that the Department of Justice will charge the company or seek a resolution from us.
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> $40 million is a staggering sum of money, especially for a development-stage life sciences company. We are acutely aware that this precious capital could have been used for many other value-creating purposes. Nevertheless, we believe that it was a necessary step so that we could focus all our attention on the development of simufilam rather than being distracted by ongoing government investigations. Make no mistake, we recognize this as a very sad chapter in Cassava's history.
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> Against this backdrop, we have taken a number of steps to enhance corporate governance, transparency, and accountability, including the separation of the CEO and Board Chair roles.

. . .

We have been asked a lot of questions about the SEC settlement and our Phase 2b study. The Phase 2b study was a 28-day trial with 64 patients across three arms that was not powered for statistical significance. Given the inherent limitations of such small sample sizes, often referred to as the tyranny of small numbers, the Company believes that it is more helpful to focus on examining the two-year Phase 2 safety study that concluded earlier this year.

The Phase 2 study enrolled 216 patients and consisted of a 12-month open-label treatment phase followed by a six-month "cognition maintenance study" at month 12 in which patients were randomized 1:1 between drug and placebo. For the last six months of the trial, all patients were again administered simufilam. Statistical analysis for the Phase 2 trial was performed by Pentara based on raw data collected at 16 clinical sites in the US.

Among the results of this Phase 2 study, 47 mild patients who took open-label simufilam continuously for 24 months experienced no mean decline in cognition as measured by ADASCog11 as a group. Another 40 mild patients who took placebo for six of the 24 months declined by a mean of one point as a group. ***During the six-month randomization period, mild patients who were administered drug showed a trend of performing better as a group than those administered placebo, though this small, randomized portion of the study was not powered for, and did not reach, statistical significance. Patients in the study with moderate Alzheimer's, including the 32 moderate patients who received simufilam treatment continuously for two years, declined in cognition much more than mild patients.***

I recommend that you review the results for yourself

. . .

None of this is meant to imply that our Phase 3 trials will generate results similar to the openlabel Phase 2 study. We won't know the outcome until later this year when we release top-line results of the first of our large, randomized, well-controlled studies.

An effective, twice-daily oral medication with a compelling safety profile would be a valuable benefit to patients, their loved ones, and physicians. Our goal is to deliver such a medication to those who suffer from this cruel disease. Our first Phase 3 clinical trial, ReTHINK, has completed dosing, and ReFOCUS is only months away from completion. ***In the meantime, nearly 90% of all Phase 3 patients (currently, more than 1,000 individuals) have elected to participate in an extension trial where they receive open-label simufilam. With results imminent, we are disheartened that some detractors would openly root for the failure of a promising potential Alzheimer's treatment.***

> We recognize the serious questions raised about some of the work performed at City University of New York, but those accusations do not negate the entire scientific body of evidence for our drug. We have previously highlighted independent research that supports the biological activity of simufilam, such as that conducted by researchers at the Cochin Institute in Paris and at Yale University. We are evaluating ways to make this information more readily accessible for journalists, investors, or anyone curious about our drug. We believe that some of our critics have mischaracterized the scientific and clinical basis supporting simufilam, while cherry-picking and taking out of context statements that we have made. We encourage interested parties to make their own determination in light of the information that we have provided
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> . . .
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> If our Phase 3 program produces success, we will have made a significant contribution to the millions of patients and their families who live with the reality of this disease. If we fail, no one will be more crestfallen than we will be, but we also will know that we have done our best. Our patients deserve no less.

November 7, 2024

37. On November 7, 2024, Cassava held published their third quarter fiscal year 2024 results. During the same-day earnings call CEO Barry provided reassurances that suggested simufilam would be successful, stating, in pertinent part:

> We expect to announce the top line results of the trial before the end of this year. ***This is an exciting time for us. We remain optimistic that we will see promising data that could ultimately lead to a best-in-class treatment for Alzheimer's, but we will all see whether our optimism is warranted or misplaced before too long.***
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> . . .
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> ***The many doctors I met decided to participate in our trials because they made their own assessment of simufilam, and they believe that based on a hypothesized mechanism of action, the drug had a reasonable chance of working***.
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> If the trials are successful, they know it would make a difference in the lives of their patients. ***These doctors live for innovation in Alzheimer's drug discovery and they want to be involved with something that could make a real difference***. They know better than anyone that there is no sure thing in Alzheimer's, but they believe the drug needed to be studied.

> Additionally, I believe they chose to be involved because of the trust they have in Jim and his remarkable team. I am really proud to be associated with this team ***and I'm truly grateful to these courageous doctors, who have given simufilam the opportunity to demonstrate its potential by participating in our trials, when it would have been so much easier to have just said no.***

(Emphasis added).

38. The above statements in Paragraphs 21 to 37 were false and/or materially misleading. Defendants created the false impression that they possessed reliable information pertaining to the Company's drug prospects and anticipated growth while also minimizing risk from a potential drug failure. Yet, in truth, Cassava's repeated statements of confidence in their drug and reliance upon spinning the statistically insignificant data from the Phase 2 study fell short of the reality of simufilam's potential; the Company simply did not have a drug that was capable of abating the progression of Alzheimer's Disease, even when attempting to treat only the mild and moderate cases.

The Truth Emerges during Cassava's Publication of its Phase 3 Topline Results

November 25, 2024

39. On November 25, 2024, Defendants published topline results for the ReThink-ALZ Phase 3 study in which simufilam failed to reach any of the study's endpoints:

> [T]he topline results from the ***Phase 3 ReThink-ALZ study of simufilam in mild-to-moderate AD did not meet each of the pre-specified co-primary, secondary and exploratory biomarker endpoints***. The co-primary endpoints were the change in cognition and function from baseline to the end of the double-blind treatment period at week 52, assessed by the ADAS-COG12 and ADCS-ADL scales, comparing simufilam to placebo. Simufilam continued to demonstrate an overall favorable safety profile

40. CEO Richard Barry spoke to the results and their implications to Cassava's other simufilam studies, stating, in pertinent part:

> The results are disappointing for patients and their families who are living with this disease and physicians who have been looking for novel treatment options. We took

> careful measures to enroll patients with mild-to-moderate AD. Despite that, the loss of cognition in the placebo group was less pronounced than was previously reported in other placebo-controlled studies in AD,. We are working to understand this better . . . ***A result like this has implications in our second Phase 3 trial, ReFocus-ALZ. We have made the difficult decision to discontinue ReFocus-ALZ, given the nature of today's reported results***. The complete 52-week dataset will be available from the study along with a large portion of 76-week data. We intend to report detailed analyses of both studies in the future. ***We will also be discontinuing the Open Label Extension study.***

(Emphasis added).

41. Later that day, Defendants held a special call to provide additional prepared remarks regarding the Phase 3 topline results. CEO Barry spoke again on the matter, stating, in pertinent part:

> As outlined in our press release, the study failed to meet each of its prespecified co-primary endpoints as well as its secondary endpoints and exploratory plasma biomarker endpoints.
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> . . .
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> We took careful measures to enroll patients with mild to moderate Alzheimer's. Despite that, the loss of cognition in the placebo group was less pronounced than was previously reported in other placebo-controlled studies in AD. We're working to understand this better. The results are disappointing for patients and their families who are living with this disease and physicians who have been looking for novel treatment options.

42. The aforementioned press releases and statements made by the Individual Defendants are in direct contrast to statements they made during and through their various press releases, quarterly reports, earnings calls, "fireside chats" and open letters to investors between February 7, 2024 and November 7, 2024. In those communications, Defendants exhibited clear confidence in simufilam's ability to treat Alzheimer's Disease through the promotion of statistically insignificant phase 2 results, patient elected enrollment in the open-label expansion studies, and the presentation of detailed plans for the future of the company upon the conclusion

of successful Phase 3 studies showing the effectiveness of simufilam, coupled with the absence of any detailed plan for the alternative scenario arising out of the drug's failure.

43. Investors and analysts reacted immediately to Cassava's revelation. The price of Cassava's common stock declined dramatically. From a closing market price of $26.48 per share on November 22, 2024, Cassava's stock price fell to $4.30 per share on November 25, 2024, a decline of about 83.76% in the span of just a single day.

44. A number of well-known analysts who had been following Cassava lowered their price targets in response to Cassava's disclosures. For example, H.C. Wainright & Co., while downgrading their rating from "Neutral" to "Buy," acknowledged they were "surprised by the results as Phase 2 studies suggested mechanism of action (MOA)-based and biomarker-based results supported high potential for a positive result with simufilam treatment vs placebo." However, the analyst goes on to acknowledge the weaknesses in the testing conditions in assessing accurate results, stating, in pertinent part, the following:

> It is known that ADAS-Cog may have ceiling effects, which means the test may not be able to detect differences between individuals who score above a certain level, especially in mild-to-moderate AD patients . . . This can make the test less sensitive to changes in cognitive impairment in the early stages of the disease

45. Similarly, Jones Research, while issuing their hold rating, summarized that the "analysis of the mild and moderate sub-groups did not demonstrate statistical significance at week 52 in either primary endpoint . . . We expected better drug effects in the mild patient subgroup but management noted that the placebo arm demonstrated lower than expected loss of cognition compared to historical outcomes in AD.

46. The fact that these analysts, and others, discussed Cassava's shortfall and below-expectation projections suggests the public placed significant weight on Cassava's prior revenue

and sales estimates. The frequent, in-depth discussion of Cassava's guidance confirms that Defendants' statements during the Class Period were material.

Loss Causation and Economic Loss

47. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Cassava's common stock and operated as a fraud or deceit on Class Period purchasers of Cassava's common stock by materially misleading the investing public. Later, Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of Cassava's common stock materially declined, as the prior artificial inflation came out of the price over time. As a result of their purchases of Cassava's common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages under federal securities laws.

48. Cassava's stock price fell in response to the corrective event on November 25, 2024, as alleged *supra*. On November 25, 2024, Defendants disclosed information that was directly related to their prior misrepresentations and material omissions concerning Cassava's sole drug, simufilam.

49. In particular, on November 25, 2024, Cassava announced the first of Phase 3 topline results regarding simufilam as a treatment for Alzheimer's Disease, noting that the drug had failed to meet any of the study's biomarker endpoints.

Presumption of Reliance; Fraud-On-The-Market

50. At all relevant times, the market for Cassava's common stock was an efficient market for the following reasons, among others:

(a) Cassava's common stock met the requirements for listing and was listed and actively traded on the NASDAQ during the Class Period, a highly efficient and automated market;

(b) Cassava communicated with public investors via established market communication mechanisms, including disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

(c) Cassava was followed by several securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and

(d) Unexpected material news about Cassava was reflected in and incorporated into the Company's stock price during the Class Period.

51. As a result of the foregoing, the market for Cassava's common stock promptly digested current information regarding the Company from all publicly available sources and reflected such information in Cassava's stock price. Under these circumstances, all purchasers of Cassava's common stock during the Class Period suffered similar injury through their purchase of Cassava's common stock at artificially inflated prices, and a presumption of reliance applies.

52. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

No Safe Harbor; Inapplicability of Bespeaks Caution Doctrine

53. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint. As alleged above, Defendants' liability stems from the fact that they provided investors with revenue projections while at the same time failing to maintain adequate forecasting processes. Defendants provided the public with forecasts that failed to account for this decline in sales and/or adequately disclose the fact that the Company at the current time did not have adequate forecasting processes.

54. To the extent certain of the statements alleged to be misleading or inaccurate may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

55. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of Cassava who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by the defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

CLASS ACTION ALLEGATIONS

56. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Cassava's common stock during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

57. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Cassava's common stock were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Cassava or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions. As of November 4, 2024, there were 48.11 million shares of the Company's common stock outstanding. Upon information and belief, these shares are held by thousands, if not millions, of individuals located throughout the country and possibly the world. Joinder would be highly impracticable.

58. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

59. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

60. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Cassava;

(c) whether the Individual Defendants caused Cassava to issue false and misleading financial statements during the Class Period;

(d) whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

(e) whether the prices of Cassava's common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

(f) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

61. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

Against All Defendants for Violations of

Section 10(b) and Rule 10b-5 Promulgated Thereunder

62. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

63. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

64. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon. Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Cassava common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Cassava's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

65. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to

influence the market for Cassava's securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company.

66. By virtue of their positions at the Company, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

67. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of the Company, the Individual Defendants had knowledge of the details of Cassava's internal affairs.

68. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of the Company. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Cassava's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements,

the market price of Cassava's common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning the Company which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Cassava's common stock at artificially inflated prices and relied upon the price of the common stock, the integrity of the market for the common stock and/or upon statements disseminated by Defendants, and were damaged thereby.

69. During the Class Period, Cassava's common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Cassava's common stock at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Cassava's common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Cassava's common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

70. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

71. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases,

acquisitions and sales of the Company's common stock during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

Against the Individual Defendants

for Violations of Section 20(a) of the Exchange Act

72. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

73. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information about Cassava's misstatements.

74. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information, and to correct promptly any public statements issued by Cassava which had become materially false or misleading.

75. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Cassava disseminated in the marketplace during the Class Period concerning the misrepresentations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Cassava to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Cassava's common stock.

76. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause Cassava to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

77. By reason of the above conduct, the Individual Defendants and/or Cassava are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class pre-judgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: December 12, 2024

Respectfully submitted,

SPONSEL MILLER GREENBERG PLLC

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-and-

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Lead Counsel for Plaintiff

Certification of Plaintiff Pursuant to Federal Securities Laws

I, Stephen F. Crocker , duly certify and say, as to the claims asserted under the federal
Name
securities laws, that:

1. I have reviewed a complaint filed in the action.

2. I did not purchase the security that is the subject of this action at the direction of plaintiff's counsel or in order to participate in this action.

3. I am willing to serve as a representative party on behalf of the class, including providing testimony at deposition and trial, if necessary.

4. My transaction(s) in Cassava Sciences, Inc. which are the subject of this litigation during the class period set forth in the complaint are set forth in the chart attached hereto.

5. Within the last 3 years, I have not sought to serve nor have I served as a class representative in any federal securities fraud case.

6. I will not accept any payment for serving as a representative party on behalf of the class beyond the Plaintiff's pro rata share of any recovery, except as ordered or approved by the court, including any award for reasonable costs and expenses (including lost wages) directly relating to the representation of the class.

I certify under penalty of perjury that the foregoing is true and correct. Executed this

12/12/2024

Date

Stephen F. Crocker

Name

Signature

Date	Purchase/Sale	Shares	Price
7/17/2024	P	200	9.1